

## **REMARKS**

Claims 1, 3, 7, 24, 25 and 29 are currently amended. Claims 1-29 are currently pending. Claims 3, 7, 10 and 20-22 are withdrawn.

Reconsideration of the application in view of the current claims is respectfully requested and further in view of the following Remarks.

### **I. EXAMINER INTERVIEW**

Applicant wishes to acknowledge, with appreciation, the courtesies extended by the Examiner during the Examiner Interview with representative James R. Shay on May 2, 2006. The Examiner's comments were helpful to Applicant in preparing this Response.

### **II. CLAIM REJECTIONS UNDER 35 U.S.C. § 102**

The Examiner has rejected claims 1, 2, 4-6, 8,9, 11-17, and 19 under 35 U.S.C. § 102(b) as being anticipated by Zang et al. (5,314,486). The Examiner asserts that:

Zang, et al discloses a prosthesis comprising a fastening element, and an artificial joint structure carried by the fastening element. While the prosthesis of Zang, et al is intended for replacement of a phalangeal type joints, the structure as broadly claimed is fully met by the prosthesis of Zang, et al. The prosthesis of an, et al is structurally similar to that illustrated by applicant. Therefor, examiner contends that the device of Zang et al is capable of performing the function of replacing all or a portion of the natural facet joint. (see, Office action, p. 3)

In order for Applicant's claims to lack novelty under 35 U.S.C. § 102 (*i.e.*, be anticipated), each and every element of the claimed invention must be disclosed in a single prior art reference. A prior art reference anticipates a claim *only if* the reference discloses, either expressly or inherently, every limitation of the claim.

The Patent Examiner bears the burden of demonstrating that Applicant's invention is anticipated by the reference relied on in the Examiner's reasons for rejection.

As the Examiner correctly notes, Zang '486 is directed towards a joint prosthetic replacement device for a metatarso-phalangeal joint (See, e.g., Zang '486 Abstract). Zang '486 does not describe how any of the components of his metatarsal – phalangeal devices are adapted to be removably attached to the vertebra as required by Applicant's claim 1. Moreover, Zang '486

does not suggest that his metatarsal-phalangeal devices are suited for anything but prosthesis of the phalangeal joints.

For the foregoing reasons, Applicant's claim 1 is not anticipated by Zang et al. under 35 U.S.C. § 102(b). However, in order to advance this application to issuance Applicant has amended claim 1 to further clarify the application of the claimed invention to the spine by reciting that the prosthetic facet joint articulating surface is dimensioned to replace all or a portion of a natural facet joint on the vertebra. Zang does not describe how any of the components of his metatarsal-phalangeal devices are dimensioned to replace all or a portion of a natural facet joint. Applicant therefore requests that the Examiner withdraw his rejection of claim 1. Furthermore, claims 2, 4-6, 8, 9, 11-17, and 19 depend directly or indirectly from claim 1 and include the limitations thereof. For the reasons provided with respect to claim 1, claims 2, 4-6, 8, 9, 11-17, and 19 are not anticipated by Zang et al. under 35 U.S.C. § 102(b). Therefore, Applicant also requests that the rejection of claims 2, 4-6, 8, 9, 11-17, and 19 under 35 U.S.C. § 102(b) be withdrawn as well.

### **III. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(A)**

During patent examination the PTO bears the initial burden of supporting a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. Mere identification in the prior art of each element is insufficient to defeat patentability of the combined subject matter. There must also be some suggestion or motivation to modify the reference or to combine reference teachings. *See* MPEP § 2142. Thus, there must be some positive, concrete evidence which gives a logical reasoning which justifies a combination of references. Further, Applicant's explanation of how the invention works does not render obvious that which is otherwise unobvious. Finally, there must be a reasonable expectation of success and the references must teach or suggest all of the claim limitations.

In practice, this requires that the Examiner explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious. Further, the factual inquiry of whether to combine references must be based on the objective evidence of record. Failure to meet that burden is a basis for the Board to overturn the obviousness rejection. The Examiner cannot simply use Applicant's teaching to show that a person of ordinary skill would have been led to the combination of references. Similarly, the Examiner cannot provide conclusory statements supporting the rejection. The motivation-suggestion-teaching requirement protects against the entry of hindsight into the obviousness analysis.

Applicant believes the Examiner has not met his burden under § 103 for the following reasons:

**A. Claims 5, 6 and 18 have been rejected under 35 U.S.C. § 103 over Zang et al. in view of Johnson et al.**

The Examiner has rejected Claim 5, 6 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Zang et al. in view of Johnson et al. The Examiner asserts that:

The combination of the fastening element and the facet joint structure of Zang et al is illustrated to be one piece. It is well known in the art to fabricate the elements, fastening and the joint structure independently to be joined later by the surgeon, as shown for example by Johnson, et al. Independent elements allow for better sizing and matching of the prosthesis to the in vivo bone structure. In view of Johnson, et al., to fabricate the one piece prosthesis of Zang, et al out of two pieces would have been obvious to one with ordinary skill in the art as the independent pieces allows the surgeon greater flexibility. (see, Office action, pp. 4-5).

As discussed above, Zang '486 does not describe how any of the components of his metatarsal – phalangeal devices are adapted to be removably attached to the vertebra as required by Applicant's claim 1. Further, Zang does not describe how any of the components of his metatarsal—phalangeal devices are dimensioned to replace all or a portion of a natural facet joint, as claimed by Applicant. Claims 5, 6 and 18 depend from claim 1 and include the limitations thereof, therefore Zang does not teach or suggest all the elements of the rejected claims.

Johnson '641 is directed towards tibial prosthesis. Nothing in Johnson teaches or suggests use within a vertebra as required by Applicant's claims or how any of the components are dimensioned to replace all or a portion of a natural facet joint, as claimed by Applicant.

Even assuming that there was a motivation in one of these references to combine Zang's phalangeal joint prosthesis with Johnson's tibial prosthesis, such a combination fails to render obvious Applicant's claim 1. Neither Zang '486 nor Johnson '641 make reference to, suggest or describe how either of their prosthesis alone or in any combination provide "a fastening element adapted to be removably attached to the vertebra or "dimensioned to replace all or a portion of a natural facet joint," as claimed by Applicant. As such, Applicant's claim is not rendered obvious by Zang '486 or Johnson '641 either alone or in any combination. Claim 1 is unobvious and allowable in view of Zang '486 and/or Johnson '641. Because claims 5, 6, and 18 all depend from claim 1, claims 5, 6 and 18 are also unobvious and allowable in view of Zang '486 and/or Johnson '641 for the same reasons. Applicant therefore requests that the rejection of dependent claims 5, 6, and 18 under 35 USC 103 in view of Zang '486 and/or Johnson '641 be withdrawn.

**B. Claim 10 has been rejected under 35 U.S.C. § 103 over Zang et al. in view of Carignan et al.**

The Examiner has rejected Claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Zang et al. in view of Carignan et al. The Examiner asserts that:

The insert of Zang et al is shown to be mechanically fixed to the fastening element using a morse taper connection. To connect the insert to the fastening element of Zang, et al with a morse taper connection would have been obvious to one with ordinary skill in the art as being essentially equivalent means for fixing an insert to a main component. (*see*, Office action, p. 5)

As discussed above, Zang '486 does not describe how any of the components of his metatarsal – phalangeal devices are adapted to be removably attached to the vertebra as required by Applicants' claim 1. Further, Zang does not describe how any of the components of his metatarsal—phalangeal devices are dimensioned to replace all or a portion of a natural facet joint, as claimed by Applicant. Claim 10 depends from claim 1 and includes the limitations thereof, therefore Zang does not teach or suggest all the elements of the rejected claims.

Carignan '916 is directed towards a thumb joint prosthesis. Nothing in Carignan teaches or suggests a fastening element adapted to be removably attached to the vertebra or show how the device would be dimensioned to replace all or a portion of a natural facet joint, as claimed by Applicant.

Again, assuming arguendo that there was a motivation in one of these references to combine Zang's phalangeal joint prosthesis with Carigan's thumb joint prosthesis, such a combination fails to render obvious Applicant's claim 1. Neither Zang '486 nor Carignan '916 make reference to, suggest or describe how either of their prosthesis alone or in any combination provide "a fastening element adapted to be removably attached to the vertebra as claimed. Nor do either of the reference show devices dimensioned to replace all or a portion of a natural facet joint, as claimed by Applicant. As such, claim 1 is not rendered obvious by Zang '486 or Carignan '916 either alone or in any combination. Thus, claim 1 is unobvious and allowable in view of Zang '486 and/or Carignan '916. Because claim 10 depends from an allowable independent claim, claim 10 is allowable for the same reasons. Applicant requests that the rejection of dependent claim 10 under 35 U.S.C. 103 in view of Zang '486 and/or Carignan '916 be withdrawn.

#### **IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 112**

The Examiner has rejected claim 29 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action, page 2). The Examiner asserts that claim 29 "should be re-worded as a Markush group."

Applicant has amended claim 29 to place it into Markush format to overcome this rejection. Accordingly, Applicant requests that the Examiner withdraw his rejection of claim 29 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

#### **V. CLAIM REJECTIONS UNDER 35 U.S.C. § 101**

The Examiner has rejected claims 24-25 under 35 U.S.C. §101 as drawn to non-statutory subject matter (Office Action, page 2). The Examiner asserts that the claims 24-25 "as worded positively recites the in vivo body structure as part of applicant's device."

Applicant has amended claims 24-25 to recite that the device is adapted to attach to the vertebra in order to overcome the Examiner's rejection. Accordingly, Applicant requests that the Examiner withdraw his rejection of claims 24-25 under 35 U.S.C. §101 as drawn to non-statutory subject matter.

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Reply to Office Action of March 13, 2006

### CONCLUSION


For the foregoing reasons, Applicant requests the Examiner allow claims 1-29 and advance the application to issuance.

### FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 29914-701.406).

Respectfully submitted,

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